



**Standard
Process®**

9124 '99 OCT -8 P3:37

September 29, 1999

10/5/99

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statement:

(1) The minerals contained in Calsol are combined with carbamide to support gall bladder function, as well as the digestive, musculoskeletal, and central nervous systems.*

This statement is made for a dietary supplement containing ingredients of calcium glycerophosphate, calcium lactate, carbamide, magnesium citrate, calcium stearate, and calcium acid phosphate. And the name of the product is Calsol®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

97S - 0162

67492

LET 4378

